(g) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (f) of this section:

1. Data on only one plant species (rice, *Oryza sativa*) are required.

2. Data are required if the risk quotient from any aquatic plant growth Tier II study exceeds a level of concern for aquatic plants.

3. Not required when:

i. There are no potential exposures to plants;

ii. The hydrolytic half-life is less than 5 days at pH 5, 7, and 9; or

iii. The results of a biodegradation study indicate that the active ingredient or principal degradation products are not biodegradable in 28 days, *i.e.*, the biodegradation curve has not reached a plateau for at least three determinations within the 28 days.

4. For TEP testing, data are required for the applicant's end-use product if an ingredient in the end-use product, other than the active ingredient, is expected to enhance the toxicity of the active ingredient.

5. One Tier II (dose response) study, conducted with *Selenastrum capricornutum,* is required for the all other use patterns category (as specified in §158.2250(c)). If the results of this study exhibit detrimental effects (EC_{50} less than 1.0 ppm or mg/L), then additional Tier II (dose response) studies are required on three species (*Anabaena flos-aquae, Navicula pelliculosa, and Skeletonema costatum).*

6. For industrial processes and water systems, antifoulant coatings and paints, wood preservatives, and aquatic areas, Tier II (dose response) studies are required on four species (*Anabaena flos-aquae, Navicula pelliculosa, Skeletonema costatum,* and *Selenastrum capricornutum*).

7. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

8. Tests are required on a case-by-case basis based on the results of lower tier plant protection studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

9. Protocols must be approved by the Agency prior to the initiation of the study.

10. For the all other use patterns category (as specified in §158.2250(c)), data are required if the aquatic (algal) plant growth Tier II study demonstrates detrimental effects at less than 1.0 ppm or mg/L.

§158.2260 Applicator exposure.

(a) *General.* Subpart B of this part and §158.2201 describe how to use the table in paragraph (d) of this section to determine the applicator exposure data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (e) of this section.

(1) The Agency may accept surrogate exposure data estimations and/or modeling estimations from other sources to satisfy exposure data requirements. The surrogate data must meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. To be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address the applicable exposure data requirements and contain adequate monitoring events of acceptable quality. The data must reflect the specific use prescribed on the label and the activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information.

(2) Occupational uses include not only handlers, mixers, loaders, and applicators, but also commercial applications to residential sites. Residential uses are limited to non-occupational, *i.e.*, non-professional, antimicrobial applications. Both occupational and residential applicator data may be required for the same product.

(b) *Criteria for testing.* Applicator exposure data described in the table to paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if at least one of the toxicity criteria in paragraph (b)(1) of this section, and at least one of the exposure criteria in paragraph (b)(2) of this section are met.

(1) *Toxicity criteria.* (i) Evidence of potentially significant adverse effects have been observed in any applicable toxicity studies.

(ii) Scientifically sound epidemiological or poisoning incident data with a clear cause-effect relationship indicating that adverse health effects may have resulted from exposure to the pesticide.

(2) *Exposure criteria.* (i) Dermal exposure may occur during product use.

(ii) Respiratory exposure may occur during product use.

(c) *Key.* R = Required; CR = Conditionally required; TEP = Typical end-use product.

(d) *Antimicrobial applicator exposure data requirements table.* The following table shows the data requirements for applicator exposure. The test notes appear in paragraph (e) of this section.

TABLE—ANTIMICROBIAL APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline No.	Data requirements	Use sites		Test substance	Test note No.
		Occupational	Residential		
875.1100	Dermal exposure	R	R	TEP	1, 2, 3, 4
875.1200					
875.1300	Inhalation exposure	R	R	TEP	1, 2, 3, 4
875.1400					
875.1500	Biological monitoring	CR	CR	TEP	1, 2, 3
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Prior to initiation of the study, protocols involving intentional exposure of human subjects must be submitted for review by EPA and then the Human Studies Review Board (HSRB) according to 40 CFR 26.1125. Examples of proposed human study research can be found in various reviews provided by the Human Studies Review Board (*http://www.epa.gov/osa/hsrb/index.htm*).

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation passive dosimetry exposure data, provided the human pharmacokinetics of the pesticide or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to the total internal dose.

3. For products with both indoor and outdoor uses, and similar conditions of use, data are generally required for the indoor applications only. However, data for outdoor uses are required if the Agency expects outdoor uses to result in greater exposure than indoor uses (e.g., higher use rates and application frequency, or longer exposure duration, or application methods/equipment create potential for increased dermal or inhalation exposure in outdoor versus indoor use sites). In certain cases, when a pesticide may be used both indoors and outdoors under dissimilar conditions of use, the Agency may require submission of applicator exposure data for both use patterns.

4. EPA will consider waiving this data requirement for antimicrobials applied via closed loading systems if the antimicrobial has a low vapor pressure.

5. Data reporting and calculations are required only if handler exposure data are required.

§ 158.2270 Post-application exposure.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (d) of this section to determine the post-application exposure data requirements for antimicrobial pesticide products. The data generated during these studies are used to determine the quantity of pesticide to which people may be exposed after application. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test, are listed in paragraph (e) of this section.